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TO: **Arkansas Medicaid Pharmacy Providers**

DATE: **September 1, 2004**

SUBJECT: **Proposed - Provider Manual Update Transmittal No. 67**

REMOVE		**INSERT**	
Section	**Date**	**Section**	**Date**
201.000	10-13-03	201.000	9-1-04
203.000 – 213.110	10-13-03	203.000 – 213.110	9-1-04
217.000 – 220.000	10-13-03	217.000 – 220.000	9-1-04
221.100	10-13-03	221.100	9-1-04
251.300 – 251.301	10-13-03	251.300 – 251.301	9-1-04

Explanation of Updates

Section 201.000 clarifies the type of pharmacy permit needed in the participation requirements for Pharmacy providers.

Section 203.000 includes new policy regarding pharmacies in non-bordering states and obsolete information has been deleted.

Section 204.000, titled “Administrative Requirements for Pharmacies”, was added to improve the organization of policy material.

Section 205.000 was added to improve the organization of policy material and was previously numbered 211.000.

Section 211.000 clarifies policy in program coverage. This section was previously numbered 210.100.

Section 212.000 contains minor grammar corrections.

Sections 213.100 and 213.110 have been included to clarify policy material regarding the monthly prescription limits and the extension of benefits.

Section 217.000 is incorporates policy regarding prescription drugs for Medicare-approved transplants. Obsolete information has been deleted.

Section 218.000, has been renamed and refers pharmacy providers to contact the EDS Pharmacy Help Desk instead of writing to the EDS Inquiry Unit.

Sections 219.000 and 220.000 clarify program coverage.

Section 221.100 updates policy regarding auditing procedures.

Sections 251.300 and 251.301 clarify policy regarding the generic upper limit cost and generic upper limit override. Obsolete information has been deleted.

Paper versions of this update transmittal have updated pages attached to file in your provider manual. See Section I for instructions on updating the paper version of the manual. For electronic versions, these changes will automatically be incorporated.

If you need this material in an alternative format, such as large print, please contact our Americans with Disabilities Act Coordinator at (501) 682-6789 or 1-877-708-8191. Both telephone numbers are voice and TDD.

If you have questions regarding this transmittal, please contact the EDS Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and Out-of-State at (501) 376-2211.

Thank you for your participation in the Arkansas Medicaid Program.

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Roy Jeffus, Director

Arkansas Medicaid provider manuals (including update transmittals), official notices and remittance advice (RA) messages are available for downloading from the Arkansas Medicaid website: **www.medicaid.state.ar.us**.

201.000 Arkansas Medicaid Participation Requirements for Pharmacy Providers 9-1-04

Providers of pharmacy services must meet the following criteria in order to be eligible for participation in the Arkansas Medicaid Program:

A. The pharmacy must complete a provider application, a Medicaid contract and a Request for Taxpayer Identification Number and Certification with the Arkansas Medicaid Program. **View or print a provider application (Form DMS-652), Medicaid contract (Form DMS-653) and Request for Taxpayer Identification Number and Certification (W-9).**

B. The pharmacy must have a current retail pharmacy permit issued by the applicable State Board of Pharmacy. A current copy of the pharmacy permit must accompany the provider application and Medicaid contract. Subsequent permits must be provided when renewed.

C. The pharmacy must have a DEA number issued by Drug Enforcement Agency. A current copy of the DEA certificate must accompany the provider application, Request for Taxpayer Identification Number and Certification, and Medicaid contract. Subsequent certificates must be provided when renewed.

D. Indian Health Services (HIS) pharmacy providers enrolled in other states' pharmacy programs will meet Arkansas enrollment criteria if they provide proof of other state enrollment.

E. The provider application and Medicaid contract must be approved by the Arkansas Medicaid Program.

203.000 Pharmacies in Non-Bordering States 9-1-04

Pharmacies in non-bordering states may be enrolled as routine services providers for prescription claims resulting from emergency services provided in a non-bordering state or for products not available in Arkansas.

NOTE: Border state Pharmacy providers who deliver services across the state line into Arkansas must maintain an Arkansas pharmacy permit on file. If you have questions regarding this policy, please contact the Arkansas State Pharmacy Board.

~~A.~~"Emergency services" are defined as inpatient or outpatient hospital services that a prudent layperson with an average knowledge of health and medicine would reasonably believe are necessary to prevent death or serious impairment of health and which, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.
Source: 42 U.S. Code of Federal Regulations §422.2 and §424.101.

Requests for enrollment as a non-bordering routine services provider must be made in writing and forwarded to Provider Enrollment. **View or print Provider Enrollment contact information**. If a pharmacy is approved to enroll as a non-bordering pharmacy provider, an Arkansas Medicaid Provider Contract must be signed and approved before reimbursement can be made. A provider number will be assigned upon receipt and approval of the application and contract.

Providers who have agreements with Medicaid to provide other services to Medicaid recipients must have a separate provider application, Medicaid contract and Request for Taxpayer Identification Number and Certification in order to provide pharmacy services. A separate provider number, exclusive to pharmacy services, is assigned.

204.000 Administrative Requirements for Pharmacies 9-1-04

A. Pharmacy providers are prohibited from offering incentives (e.g., discounts, rebates, refunds or any other similar gratuity) for the purpose of soliciting the patronage of Medicaid recipients. (See Section I of this manual.)

B. Pharmacies may be required to participate in studies as the Department of Human Services deems necessary in order to maintain an equitable program.

C. In order to maintain program integrity, the Arkansas Division of Medical Services has the right to collect medication samples from the recipients (or long-term care facility, if a recipient is a patient there).

D. Information regarding ownership or financial interest and the identity of any agent or managing employee convicted of a Medicaid-related offense must be provided to the Arkansas Division of Medical Services within thirty (30) days of a written request.

205.000 Regulations and Procedures Governing Payment to Pharmacies for Pharmaceutical Services for Eligible Medicaid Recipients 9-1-04

A. Clozapine must be billed as one prescription for a month's supply. Medicaid must be billed when the first week's supply is given. If the patient does not receive a full month's supply, the claim can be adjusted at the end of the month to the quantity actually dispensed to the patient.

B. When a Medicaid recipient receives BetaSeron for ten consecutive months, the manufacturer will provide a two-month supply free of charge. Providers can not bill Medicaid for the two (2) free months.

210.000 PROGRAM COVERAGE 10-13-03

211.000 Scope 9-1-04

The Arkansas Medicaid Pharmacy Program conforms to the Medicaid Prudent Pharmaceutical Purchasing Program (MPPPP) that was enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1990. **This law requires Medicaid to limit coverage to drugs manufactured by pharmaceutical companies that have signed rebate agreements.** A numeric listing of approved pharmaceutical companies and their respective labeler codes is located on the Arkansas Division of Medical Services (DMS) Web site at **www.medicaid.state.ar.us**. **View or print numeric listing of approved pharmaceutical companies and their respective labeler codes.** Except for drugs in the categories excluded from coverage, Arkansas Medicaid covers all drug products manufactured by companies with listed labeler codes. As additions or deletions by labelers are submitted to the State by the Centers for Medicare and Medicaid Services (CMS), the Web site will be updated.

The Arkansas Medicaid Program will cover the following drug categories:

A. Prescription drugs are covered by the Arkansas Medicaid Program pursuant to an order from an authorized prescriber. The Multisource Drugs Listing located on the DMS Web site at **www.medicaid.state.ar.us** lists those products covered by the Arkansas Medicaid Program that have a generic upper limit (See Section 251.300 for an explanation of generic upper limit.)

As changes are made to the drug coverage, providers will be notified of the revisions.

B. Over-the-counter items are listed on the Web site at **www.medicaid.state.ar.us**. These items are covered only if they contain an appropriate National Drug Code on their label and are manufactured by a company that has signed a rebate agreement. Over-the-counter items are not covered for long-term care facility residents. **View or print a list of over-the-counter items.**

NOTE: The Arkansas Medicaid Program will cover the above-listed vaccines only for Medicaid recipients age 21 years and older.

C. For individuals age 21 years and older, the Arkansas Medicaid Program will reimburse pharmacies the cost of administering, by injection, two types of vaccines:

1. Influenza virus vaccine, whole virus, for intramuscular or jet injection use and
2. Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, for subcutaneous or intramuscular use.

A prescription order from an authorized prescriber must be on file; however, no primary care physician (PCP) referral is required to administer the vaccines.

These vaccines are payable for Medicaid-eligible recipients age 21 years and older. The influenza virus vaccine is limited to one per state fiscal year (July through June). The pneumococcal polysaccharide vaccine is limited to one every ten years.

Medicaid will reimburse the Medicare deductible and/or coinsurance for all recipients receiving both Medicare and Medicaid benefits.

Pharmacies must use the CMS-1500 (formerly HCFA-1500) claim form when billing Medicaid for these vaccines.

212.000 Exclusions 9-1-04

A. Products manufactured by non-rebating pharmaceutical companies are not covered by the Arkansas Medicaid Pharmacy Program.

B. The following categories of drugs are not covered in the Arkansas Medicaid Pharmacy Program:

1. Agents used for weight reduction
2. Agents used to promote fertility
3. Agents used for cosmetic purposes (including acne preparations) or hair growth
4. Agents used to promote smoking cessation, with the exception of Zyban, which requires prior authorization
5. Vitamins and mineral products, except prescription prenatal vitamins for pregnant women only and prescription fluoride preparations. See **www.medicaid.state.ar.us** for a list of possible exceptions.
6. Drugs that have been determined by the FDA to be ineffective and have DESI ratings of 5 or 6
7. Sedatives and hypnotics in the benzodiazepine category except Dalmane, Doral, Halcion, Prosom and Restoril (brand name or generic, depending on whether the drug has a generic upper limit)
8. Devices except disposable insulin syringes, insulin needles, condoms and diaphragms
9. Supplies
10. Over-the-counter products except those included in the Covered Over-the-Counter (OTC) Products list. **View or print Covered Over-the-Counter Products list.** OTC products are not covered for long-term care facility residents.
11. Limited cough and cold preparations are covered only for Medicaid-eligible recipients under the age of 21 years. Prescription cough and cold preparations are covered for certified long-term care recipients. **View or print a list of cough and cold preparations.**
12. Vaccines, except for the influenza virus and pneumococcal polysaccharide vaccines (See Section 210.100 of this manual.)
13. Medical accessories are not covered under the Arkansas Medicaid Pharmacy Program. Typical examples of medical accessories are atomizers, nebulizers, hot water bottles, fountain syringes, ice bags and caps, urinals, bedpans, glucose monitoring devices and supplies, cotton, gauze and bandages, wheelchairs, crutches, braces, supports, diapers and nutritional products.

213.000 Benefit Limits 10-13-03

213.100 Monthly Prescription Limits 9-1-04

A. Each prescription for all Medicaid-eligible recipients may be filled for up to a maximum thirty-one-day supply. Maintenance medications for chronic illnesses must be prescribed and dispensed in quantities sufficient (not to exceed the maximum 31-day supply per prescription) to effect optimum economy in dispensing. For drugs that are specially packaged for therapy exceeding 31 days, the days supply limit (other than 31), as approved by the Agency, will be allowed for claims processing. Contact the Pharmacy Help Desk to inquire about specific days supply limits on specially packaged dosage units. **View or print the EDS Pharmacy Help Desk contact information.**

B. Each Medicaid-eligible recipient age 21 years and older is limited to three (3) Medicaid-paid prescriptions per calendar month.

Each prescription filled counts toward the monthly prescription limit except for the following:

1. Family planning items. This includes, but is not limited to, birth control pills, contraceptive foams, contraceptive sponges, suppositories, jellies, prophylactics and diaphragms.
2. Prescriptions for Medicaid-eligible long-term care facility residents. (Prescriptions must be for Medicaid-covered drugs.)
3. Prescriptions for Medicaid-eligible recipients under age 21 in the Child Health Services/Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Program. (Prescriptions must be for Medicaid-covered drugs.)

213.110 Extension of Benefits 9-1-04

The Arkansas Medicaid Program will consider extensions of the prescription drug monthly benefit limit up to a maximum of six (6) prescriptions per calendar month for recipients age 21 and older for medically necessary maintenance medications. Discretion and ethical standards are to be used when applying for an extension of the prescription drug benefit. This is especially true when the drugs considered for the extension are controlled medications. If a provider suspects an abuse of the extension of the prescription drug benefit, the Arkansas Medicaid Pharmacy Program should be contacted. The Pharmacy Program may elect to terminate extensions that are not consistently being used for appropriate maintenance therapy.

Living Choices Medicaid recipients are eligible for three (3) prescription drugs per calendar month, plus an extension of the prescription drug benefit limit up to a maximum of nine (9) Medicaid-covered prescription drugs per month. (See **www.medicaid.state.ar.us** for instructions on how to apply for an extension of prescription benefit.)

After the recipient has received the maximum monthly benefit or the maximum monthly extended benefit, he or she will be responsible for paying for his or her own medications for the remainder of the month.

217.000 Prescription Drugs for Medicare-Approved Transplants 9-1-04

Medicare Part B has coverage for prescription drugs used in immunosuppressive therapy and pharmacy providers are required to bill Medicare as a primary carrier. Pharmacy providers will receive the error code 2820 when billing an immunosuppressant drug for persons with Medicare Part B. If Medicare denies the claim, the pharmacy will receive an explanation of benefits from Medicare notifying the provider that a claim is denied by Medicare. At that time, the claim can be submitted to Medicaid as a pharmacy claim by entering the Medicare denial date into the Third Party Liability (TPL) denial date field. Medicaid will then pay the claim according to the fee schedule for that national drug code (NDC).

Pharmacy providers will need to enroll with Arkansas Medicaid as a Durable Medical Equipment (DME) provider and a Medicare provider by calling or sending a written request to the National Supplier Clearinghouse. **View or print Provider Enrollment contact information**. **View or print the National Supplier Clearinghouse contact information.**

Medicaid requires that drug records, (e.g., purchase invoices, official dispensing records, prescriptions and inventory records) must be kept in a manner that is readily retrievable, and retained for at least five (5) years or until all issues are resolved regarding audits, litigations, appeals, etc. Medicaid will conduct audits to review the TPL denial rate overrides as well as other Medicare required documentation.

218.000 Participating Manufacturer/Distributor Listing 9-1-04

Due to the importance of maintaining accurate prices in the drug master file, it is necessary that drug companies keep various drug pricing contractors informed of all product and price revisions. The Arkansas Medicaid Program's fiscal agent contracts with First DataBank pricing service to provide pricing information. It is the pharmacists' responsibility to contact the EDS Pharmacy Help Desk to determine if a manufacturer's products are listed in the First DataBank Drug File. **View or print EDS Pharmacy Help Desk contact information.**

219.000 Use of Generic Drugs 9-1-04

When a pharmacist receives a prescription for a brand- or trade-name drug, the pharmacist must:

A. Dispense the lower-cost generically equivalent drug product, when available. However, this does not prevent the recipient from purchasing the brand- or trade-name product if they choose to pay for the prescription.

or

B. If the brand-name drug has a federal or state generic-upper-limit price, the pharmacist may dispense the brand-name product but will only be reimbursed at the generic upper limit. (See **www.medicaid.state.ar.us** for an explanation of generic upper limit.)

220.000 Utilization Review 9-1-04

Drug utilization review procedures have been established for program control. It is expected that with the cooperation of provider pharmacists, high standards of patient care may be achieved through the promotion of rational drug therapy.

The pharmacist assumes professional responsibility in dispensing drugs to eligible recipients under the Medicaid Program. He or she may refuse to dispense any prescription that appears to be improperly executed or, in his or her professional judgment, is unsafe as presented. He or she may refuse to dispense drugs to known addicts or to persons known to "shop" for physicians or pharmacies in an effort to obtain more drugs than one physician would authorize.

Prospective Drug Utilization Review (ProDUR) alerts will provide for a review of drug therapy at the point of sale where each prescription is filled to allow the pharmacist to make sound professional judgment decisions concerning any potential drug therapy problems. The pharmacist may override the ProDUR alert, after professional consideration of the information, if an override is necessary for the health and well-being of the recipient. All information pertaining to ProDUR overrides is retained on file with Medicaid.

221.100 Auditing Procedures 9-1-04

Each Medicaid-enrolled pharmacy provider will be subject to an audit of their records at any time. Providers must make available to the representatives of the Division of Medical Services, or their designated agents, all required records at the time of an audit. All documentation must be available at the provider's place of business. If an audit determines that recoupment is necessary, pharmacies must present any dispute of the findings within thirty (30) days after the date of the recoupment notice.

Auditors will make announced or unannounced audits of providers. Pharmacies are encouraged to develop and maintain record-keeping standards to ensure the accessibility of required records by any member of the pharmacy staff. The absence of the pharmacy owner or manager is not a valid reason for unavailability of records. Documentation provided to the State after the audit is complete is too late for consideration. To avoid imposition of sanctions due to failure to provide requested records, pharmacies must ensure that the auditors receive the following information within a timely manner:

A. Accommodations and Records Provided to Auditors

The pharmacist on duty shall disclose the following information in whatever medium it is maintained upon request to the auditor including but not limited to:

1. Working space
2. Daily logs of all Medicaid and non-Medicaid prescriptions
3. Access to computer terminal
4. Working demonstration of computer system used by the pharmacy
5. Original prescriptions ("hard copies") of Medicaid and non-Medicaid customers (for purposes of confirming billed information, pricing and brand medically necessary documentation)
6. A completed questionnaire regarding pharmacy pricing/discount policies, services, staffing, and computer capabilities
7. Signature logs signed by the persons picking up or accepting delivery of Medicaid prescriptions and
8. Third party explanation of benefits (EOB's) to document claim denial by the third party

B. Pricing Documentation

Routine audits consist of the following:

1. Verification of the claim information, including but not limited to:
   a. Recipient's name
   b. Dates of service
   c. Drug dispensed
   d. Drug description
   e. Drug strength
   f. Quantity dispensed
   g. Directions by prescriber, and
   ~~g.~~h. Brand and package size of drug dispensed
2. Verification that the pharmacy's usual and customary charges are consistent with the Medicaid Program and the general public. Items that must be considered include but are not limited to:

a. Verification that the pricing method used for at least 90% of the private-pay prescriptions is consistent with charges to the Medicaid Program.

   Price variations in individual drugs and quantity will be noted. When a price for a prescription varies more than 10 percent within a given time frame, auditors will select the most prevalent price as usual and customary.

   Auditors may request certain documentation regarding pricing to private-pay customers (e.g., paid prescription histories in computer-generated form).

b. Verification of the shelf price of over-the-counter items.

c. Verification that all available prescription discounts are extended to the Medicaid Program.

The Medicaid Program will recoup any overpayment made as a result of a pharmacy's violation of the usual and customary billing requirement.

C. Coupons

All providers who offer coupon discounts must provide written notification to the Arkansas Division of Medical Services within 30 days before the coupon's effective date. **View or print the Arkansas Division of Medical Services address.**

Auditors will check to ensure that the prescriptions filled during the effective period of the coupon are in compliance with Pharmacy Program regulations.

D. Purchase Verification

Auditors will verify that the pharmacy has purchased the drug products (actual National Drug Codes) that have been billed to the Arkansas Medicaid Program. Pharmacies will, upon request, order purchase histories from their major wholesale vendors.

Pharmacies must make available all invoices for the requested period to facilitate auditor verification of drug purchases.

251.300 Generic Upper Limit Cost 9-1-04

The generic upper limit (GUL) price is the maximum drug cost used to compute reimbursement for multiple-source drugs unless the provisions for a generic-upper-limit override have been met.

For several multiple-source drugs, the federal government requires that payment under the Medicaid Program be based on a generic-upper-limit cost that is established by CMS. For other multiple-source drugs, the state agency has determined which drugs will be on the Arkansas generic-upper-limit list and is responsible for setting the maximum price the provider may use as his cost for that drug. The generic upper limit is listed on the Arkansas Medicaid Web site, **www.medicaid.state.ar.us**.

Generic upper limit is based on price per unit (ml, gm, tablet, capsule, etc.) in the commonly available quantity.

251.301 Generic Upper Limit Override 9-1-04

The prescriber must determine whether the Medicaid recipient meets the required conditions to override a generic upper limit (GUL) cost of a drug. The prescriber must also complete the required MedWatch (see below) documentation to allow a prior authorization (PA) for a "Brand Medically Necessary" override of the GUL to reimburse at the brand name average wholesale price (AWP).

MedWatch is the Food and Drug Administration (FDA) Safety Information and Adverse Event Reporting Program that allows healthcare professionals to report serious problems that they suspect are associated with certain drugs they prescribe.

The prescriber must obtain the prior authorization (PA) for a "Brand Medically Necessary" override by accessing the Voice Response System (VRS) for non-MedWatch drugs (carbamazepine, primidone, valproic acid and warfarin). A PA number and date range of the approved PA will be issued to the prescriber at the time of the VRS transaction. The prescriber must include the PA number and date range on the recipient's written prescription.

The following criteria must be met to override the generic upper limit cost restriction when calculating the allowable amount of reimbursement:

A. For MedWatch drugs, the following conditions are required for approval of a Brand Medically Necessary override:

1. The prescriber shall establish that the recipient's condition meets the definition provided for the medical necessity of dispensing any brand name drug when a generic equivalent is available.

   In the context of this policy, "Brand Medically Necessary" is defined as the necessity to prescribe and dispense a brand-name medication when use of a generic product has resulted in adverse reaction(s) to the generic, allergic reaction(s) to the generic or therapeutic failure of the generic.

   a. Adverse reaction caused by a generic must meet one of the following criteria:
      1. Life Threatening
      2. Hospitalization
      3. Disability
      4. Required intervention to prevent impairment or damage

   b. Allergic reaction is defined as when an allergen is present in a generic drug that is not present in a brand drug resulting in a hypersensitive reaction.

   c. Therapeutic failure is defined as, clinical failure due to the recipient's suboptimal plasma drug concentration for the generic drug when compared to published full pharmacokinetic profiles for the brand name drug.

2. The prescriber shall submit documentation to EDS using the FDA MedWatch form to support dispensing a brand-name medication instead of the generic equivalent, with the exception of the following non-MedWatch drugs:
    a. Carbamazepine
    b. Primidone
    c. Valproic acid
    d. Warfarin
3. When a MedWatch drug is approved for a Brand Medically Necessary override, the EDS Pharmacy Help Desk will contact the pharmacy provider to inform them of the prior authorization number and the date range of the approved PA.

The PA is given for up to one year for MedWatch Drugs and up to six months for non-MedWatch drugs.

All prescriptions must be on file for review by auditors from the Division of Medical Services or their designated agents.

If the criteria stated above are met and the pharmacy claim is submitted with a code of “1” in the dispense as written (DAW) field, the prescription will be priced using the EAC price for the specific product dispensed rather than the generic upper limit price.